

UNITED STATES DISTRICT COURT
DISTRICT NEW JERSEY

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DOROTHY M. PADRICK,
EXECUTRIX OF THE ESTATE OF
GRAHAM PADRICK

Civil action No. _____

Plaintiff,

COMPLAINT AND
JURY DEMAND

v.

JANSSEN RESEARCH & DEVELOPMENT, LLC
f/k/a JOHNSON AND JOHNSON
PHARMACEUTICAL RESEARCH AND
DEVELOPMENT LLC, JANSSEN ORTHO, LLC,
JANSSEN PHARMACEUTICALS, INC. f/k/a
JANSSEN PHARMACEUTICA INC. f/k/a ORTHO-
MCNEIL-JANSSEN PHARMACEUTICALS, INC.,
BAYER HEALTHCARE PHARMACEUTICALS,
INC., BAYER PHARMA AG, BAYER
CORPORATION, BAYER HEALTHCARE, LLC,
BAYER HEALTHCARE AG, and BAYER AG,

Defendants.
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Plaintiff, by and through the undersigned counsel, on behalf of herself and as Executrix of the Estate of Graham Padrick, upon information and belief, at all times hereinafter mentioned, alleges as follows:

JURISDICTION AND VENUE

1. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiff exceeds \$75,000.00, exclusive of interest and costs, and because there is complete diversity of citizenship between the Plaintiff and the Defendants.

2. Venue is proper in this jurisdiction pursuant to 28 U.S.C. § 1391, because several defendants have their principal place of doing business in this District.

3. This Court has personal jurisdiction over the Defendants because they are incorporated or have their principal headquarters in New Jersey or because they do business in this state. The Defendants actively sell, market and promote their pharmaceutical product Xarelto to physicians and consumers in this state on a regular and consistent basis.

NATURE OF THE CASE

4. This action is brought on behalf of Decedent Graham Padrick by Plaintiff Dorothy M. Padrick. Decedent was prescribed Xarelto, also known as rivaroxaban, because of a diagnosis of atrial fibrillation.

5. Defendants, JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a JOHNSON AND JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT LLC, JANSSEN ORTHO LLC, JANSSEN PHARMACEUTICALS, INC. f/k/a JANSSEN PHARMACEUTICA INC. f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., BAYER HEALTHCARE PHARMACEUTICALS, INC., BAYER PHARMA AG, BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER HEALTHCARE AG, and BAYER AG (hereinafter collectively referred to as "Defendants") designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Xarelto, as well as dealt with governmental regulatory bodies.

6. In written information about the safety and risks of Xarelto, Defendants negligently and fraudulently represented to the medical and healthcare community, including Decedent's prescribing doctor, the Food and Drug Administration (hereinafter referred to as the "FDA"), to Decedent and the public in general, that Xarelto had been tested and was found to be safe and effective for its indicated uses.

7. Defendants concealed their knowledge of Xarelto's defects, from Decedent, the FDA, the public in general and the medical community, including Decedent's prescribing doctor.

8. These representations were made by Defendants with the intent of defrauding and deceiving Decedent, the public in general, and the medical and healthcare community including Decedent's prescribing doctor, and were made with the intent of inducing the public in general, and the medical community in particular, to recommend, dispense and purchase Xarelto, all of which evinced a callous, reckless, willful, depraved indifference to health, safety and welfare of the Decedent herein.

9. Defendants negligently and improperly failed to perform sufficient tests on humans using Xarelto during clinical trials, forcing Decedent, and Decedent's physicians, hospitals, and the FDA, to rely on safety information that applies to other non-valvular atrial fibrillation treatment and DVT/PE treatment and prophylaxis, which did not entirely or necessarily apply to Xarelto.

10. As a result of the foregoing acts and omissions, the Decedent was caused to suffer serious and dangerous side effects including life-threatening bleeding, physical pain and mental anguish, including diminished enjoyment of life and death.

PARTY PLAINTIFF

11. Decedent at all times relevant hereto, was a citizen and resident of the State of Rhode Island, who suffered personal injuries, including death, as a result of his use of Xarelto.

12. Plaintiff, Dorothy M. Padrick was the wife of Decedent and duly appointed Executrix of the Estate by virtue of a Certification of Appointment May 23, 2013 by the Probate Court of the City of Cranston.

13. Decedent's estate is being administered under the probate laws of Rhode Island.

14. Upon information and belief, Decedent was prescribed Xarelto in Rhode Island from January 2013 until February 2013, upon direction of his physician for the treatment of atrial fibrillation.

15. As a direct and proximate result of the use of Defendants' Xarelto, Decedent experienced a cerebral hemorrhage and stroke in February 2013 and sustained a life-threatening, irreversible bleed from the use of Xarelto, as well as severe pain and suffering, all of which cumulated in his death on February 14, 2013.

16. As a direct and proximate result of Defendants' conduct, Plaintiff has suffered and incurred damages, including medical expenses; the loss of accumulations; funeral expenses; probate, attorney, account, and other fees and cost of administration; and other economic and non-economic damages flowing from the death of the Decedent.

PARTY DEFENDANTS

17. Upon information and belief, Defendant JANSSENRESEARCH & DEVELOPMENT LLC f/k/a JOHNSON AND JOHNSON RESEARCH AND DEVELOPMENT LLC (hereinafter referred to as "JANSSEN R&D") is a limited liability company organized under the laws of New Jersey, with a principal place of business at One Johnson & Johnson Plaza, New Brunswick, Middlesex County, New Jersey 08933. Defendant JANSSEN R&D is the holder of the approved New Drug Application ("NDA") for Xarelto as well as the supplemental NDA.

18. As part of its business, JANSSEN R&D is involved in the research, development, sales, and marketing of pharmaceutical products including Xarelto and rivaroxaban.

19. At all relevant times, Defendant, JANSSEN R&D, was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug Xarelto for use as an oral anticoagulant.

20. Defendant JANSSEN PHARMACEUTICALS, INC. f/k/a JANSSEN PHARMACEUTICA INC. f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. (hereinafter referred to as "JANSSEN PHARM") is a Pennsylvania corporation, having a principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

21. At all relevant times, Defendant, JANSSEN R&D, was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug Xarelto for use as an oral anticoagulant.

22. Defendant, JANSSEN PHARM has transacted and conducted business in New Jersey.

23. Defendant, JANSSEN PHARM, has derived substantial revenue from goods and products used in New Jersey.

24. Defendant, JANSSEN PHARM, expected or should have expected its acts to have consequence within the United States of America and the State of New Jersey, and derived substantial revenue from interstate commerce within the United States and the State of New Jersey, more particularly.

25. Defendant, JANSSEN PHARM, was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug Xarelto for use as an oral anticoagulant.

26. Defendant JANSSEN ORTHO LLC (hereinafter referred to as "JANSSEN ORTHO") is a limited liability company organized under the laws of Delaware, having a principal place of business at State Road 933 Km 0 1, Street Statero, Gurabo, Puerto Rico 00778. Defendant JANSSEN ORTHO is a subsidiary of Johnson & Johnson.

27. As part of its business, JANSSEN ORTHO is involved in the research, development, sales, and marketing of pharmaceutical products including Xarelto and rivaroxaban.

28. Defendant, JANSSEN ORTHO has transacted and conducted business in the State of New Jersey.

29. Defendant, JANSSEN ORTHO, has derived substantial revenue from goods and products used in the State of New Jersey.

30. Defendant, JANSSEN ORTHO, expected or should have expected its acts to have consequence within the United States of America and the State of New Jersey, and derived substantial revenue from interstate commerce within the United States and the State of New Jersey, more particularly.

31. Defendant, JANSSEN ORTHO, was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug Xarelto for use as an oral anticoagulant.

32. Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. is, and at all relevant times was, a corporation organized under the laws of the State of Delaware, with its principal place of business in the State of New Jersey.

33. Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. was formerly known as Berlex Laboratories, Inc., which was formerly known as Berlex, Inc. and BAYER HEALTHCARE PHARMACEUTICALS, INC. is the same corporate entity as Berlex, Inc. and Berlex Laboratories, Inc.

34. As part of its business, BAYER HEALTHCARE PHARMACEUTICALS, INC. IS involved in the research, development, sales, and marketing of pharmaceutical products including Xarelto (rivaroxaban).

35. Defendant, BAYER HEALTHCARE PHARMACEUTICALS, INC., was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug Xarelto for use as an oral anticoagulant.

36. Defendant BAYER PHARMA AG IS a pharmaceutical company domiciled in Germany.

37. Defendant BAYER PHARMA AG is formerly known as Bayer Schering Pharma AG and is the same corporate entity as Bayer Schering Pharma AG. Bayer Schering Pharma AG is formerly known as Schering AG and is the same corporate entity as Schering AG.

38. Schering AG was renamed Bayer Schering Pharma AG effective December 29, 2006.

39. Bayer Schering Pharma AG was renamed BAYER PHARMA AG effective July 1, 2011.

40. As part of its business, BAYER PHARMA AG is involved in the research, development, sales, and marketing of pharmaceutical products including Xarelto (rivaroxaban).

41. Defendant, BAYER PHARMA AG, has transacted and conducted business in the State of New Jersey.

42. Defendant, BAYER PHARMA AG, has derived substantial revenue from goods and products used in the State of Rhode Island.

43. Defendant, BAYER PHARMA AG, expected or should have expected its acts to have consequence within the United States of America and the State of New Jersey, and derived substantial revenue from interstate commerce within the United States and the State of New Jersey, more particularly.

44. Defendant, BAYER PHARMA AG, was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug Xarelto for use as an oral anticoagulant.

45. Defendant BAYER CORPORATION is an Indiana corporation with its principal place of business at 100 Bayer Road, Pittsburgh, Pennsylvania 15205.

46. Defendant BAYER CORPORATION is the sole member of BAYER HEALTHCARE LLC, which owns 100% of Schering Berlin, Inc., which owns 100% of Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. As such, Defendant BAYER CORPORATION is a parent of Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC.

47. Defendant BAYER CORPORATION was engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and introducing

into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Xarelto.

48. Defendant BAYER CORPORATION conducted regular and sustained business in the State of New Jersey, by selling and distributing its products in the State of New Jersey and engaged insubstantial commerce and business activity in the State of New Jersey.

49. Defendant BAYER HEALTHCARE LLC is a limited liability company duly formed and existing under and by the virtue of the laws of the State of Delaware, with its principal place of business located in the State of New Jersey.

50. Defendant BAYER HEALTHCARE LLC was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute Xarelto for use as an oral anticoagulant.

51. Defendant BAYER HEALTHCARE AG is a company domiciled in Germany and is the parent/holding company of Defendants BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER HEALTHCARE PHARMACEUTICALS, INC, and BAYER PHARMA AG.

52. Defendant BAYER HEALTHCARE AG has transacted and conducted business in the State of New Jersey, and derived substantial revenue from interstate commerce.

53. Defendant BAYER HEALTHCARE AG expected or should have expected that its acts would have consequences within the United States of America, and in the State of New Jersey, and derived substantial revenue from interstate commerce.

55. Defendant BAYER HEALTHCARE AG exercises dominion and control over Defendants BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER HEALTHCARE PHARMACEUTICALS, INC., and BAYER PHARMA AG.

56. Defendant BAYER AG is a German chemical and pharmaceutical company that is headquartered in Leverkusen, North Rhine-Westphalia, Germany.

57. Defendant BAYER AG is the third largest pharmaceutical company in the world.

58. Defendant BAYER AG is the parent/holding company of all other named Defendants.

59. Defendant BAYER AG has transacted and conducted business in the State of New Jersey, and derived substantial revenue from interstate commerce.

60. Defendant BAYER AG expected or should have expected that its acts would have consequences within the United States of America, and in the State of New Jersey, and derived substantial revenue from interstate commerce.

61. Defendant BAYER AG was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute Xarelto for use as an oral anticoagulant.

FACTUAL BACKGROUND

62. At all relevant times, Defendants were in the business of and did design, research, manufacture, test, advertise, promote, market, sell and distribute Xarelto (rivaroxaban) as an oral anticoagulant.

63. Defendants received FDA approval for Xarelto (rivaroxaban), on July 1, 2011 for the prophylaxis of DVT and PE in patients undergoing hip replacement or knee replacement surgeries (NDA 022406).

64. Defendants then received additional FDA approval for Xarelto to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation on November 4, 2011 (NDA 202439).

65. The additional indication for treatment of DVT and PE and the reduction in recurrence of DVT and PE was added to the label on November 2, 2012.

66. Defendants launched Xarelto in the United States (hereinafter referred to as the "U.S.") in 2011.

67. Xarelto is an anticoagulant that acts as a Factor Xa inhibitor, and is available by prescription in oral tablet doses of 20mg, 15mg, and 10mg.

68. Approval of Xarelto for the prophylaxis of DVT and PE in patients undergoing hip replacement or knee replacement surgeries was based on a series of clinical trials known as the Regulation of Coagulation in Orthopedic Surgery to Prevent Deep Venous Thrombosis and Pulmonary Embolism studies (hereinafter referred to as the "RECORD" studies). The findings of the RECORD studies showed that rivaroxaban was superior to enoxaparin for thromboprophylaxis after total knee and hip arthroplasty (based on the Defendants' definition), accompanied by similar rates of bleeding. However, the studies also showed a greater incidence

with Xarelto of bleeding leading to decreased hemoglobin levels and transfusion of blood. (Lassen, M.R., et al. Rivaroxaban versus Enoxaparin for Thromboprophylaxis after Total Knee Arthroplasty. *N. Engl. J. Med.* 2008; 358:2776-86; Kakkar, A.K., et al. Extended duration rivaroxaban versus short-term enoxaparin for the prevention of venous thromboembolism after total hip arthroplasty: a double-blind, randomized controlled trial. *Lancet* 2008; 372:31-39; Erickson, B.I., et al. Rivaroxaban versus Enoxaparin for Thromboprophylaxis after Hip Arthroplasty. *N. Engl. J. Med.* 2008; 358:2765-75.)

69. Approval of Xarelto for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation in the U.S. was based on a clinical trial known as the Rivaroxaban Once Daily Oral Direct Factor Xa Inhibition Compared with Vitamin K Antagonism for Prevention of Stroke and Embolism Trial in Atrial Fibrillation study (hereinafter referred to as "ROCKET AF"). The study's findings showed that rivaroxaban was noninferior to warfarin for the prevention of stroke or systemic embolism in patients with non-valvular atrial fibrillation, with a similar risk of major bleeding. However, "bleeding from gastrointestinal sites, including upper, lower, and rectal sites, occurred more frequently in the rivaroxaban group, as did bleeding that led to a drop in the hemoglobin level or bleeding that required transfusion." (Patel, M.R., et al. Rivaroxaban versus Warfarin in Nonvalvular Atrial Fibrillation. *N. Engl. J. Med.* 2011;365:883-91.)

70. Approval of Xarelto for the treatment of DVT and PE and the reduction in recurrence of DVT and PE in the U.S. was based on the clinical trials known as the EINSTEIN-DVT, EINSTEIN-PE, and EINSTEIN-Extension studies. The EINSTEIN-DVT study tested Xarelto versus a placebo, and merely determined that Xarelto offered an option for treatment of DVT, with obvious increased risk of bleeding events as compared to placebo. (The EINSTEIN Investigators. *Oral Rivaroxaban for Symptomatic Venous thromboembolism*. *N. Engl. J. Med.* 2010; 363:2499-510); The EINSTEIN-Extension study confirmed that result. (Roumualdi, E., et al. Oral rivaroxaban after symptomatic venous thromboembolism: the continued treatment study (EINSTEIN-Extension study). *Expert Rev. Cardiovasc. Ther.* 2011; 9(7):841-844). The EINSTEIN-PE study's findings showed that a rivaroxaban regimen was non-inferior to the standard therapy for initial and long-term treatment of PE. However, the studies also demonstrated an increased risk of adverse events with Xarelto, including those that resulted in permanent discontinuation of Xarelto or prolonged hospitalization. (The EINSTEIN- PE Investigators. *Oral Rivaroxaban for the Treatment of*

Symptomatic Pulmonary Embolism. N.Engl. J. Med. 012;366:1287-97.)

71. Defendants use the results of the ROCKET AF study, the RECORD studies, and the EINSTEIN studies to promote Xarelto in their promotional materials, including the Xarelto website, which tout the positive results of those studies. However, Defendants' promotional materials fail to similarly highlight the increased risk of hemorrhaging and resultant death.

72. Defendants market Xarelto as a new oral anticoagulant treatment alternative to warfarin (Coumadin), a long-established safe treatment for preventing stroke and systemic embolism, in 60 years. Defendants emphasize the supposed benefits of treatment with Xarelto over warfarin, which they refer to as the Xarelto Difference - namely, that Xarelto does not require periodic monitoring with blood tests and does not limit a patient's diet.

73. However, in its Quarter Watch publication for the first quarter of the 2012 fiscal year, the Institute for Safe Medication Practices ("ISMP") noted that, even during the approval process, FDA "[r]eviewers also questioned the convenient once-a-day dosing scheme [of Xarelto], saying blood level studies had shown peaks and troughs that could be eliminated<by twice-a-day dosing."

74. Critically, there is no antidote to Xarelto, unlike warfarin. Therefore, in the event of hemorrhagic complications, there is no available reversal agent. The U.S. label approved when the drug was first marketed in the U.S. did not contain a warning regarding the lack of antidote, but instead only mentioned this in the overdose section.

75. Defendants spent significant money in promoting Xarelto, which included at least \$11,000,000.00 spent during 2013 alone on advertising in journals targeted at prescribers and consumers in the U.S. In the third quarter of the 2013 fiscal year, Xarelto was the number one pharmaceutical product advertised in professional health journals based on pages and dollars spent.

76. As a result of Defendants' aggressive marketing efforts, in its first full year of being on the market, Xarelto garnered approximately \$582 million in sales globally.

77. Defendants' website for Xarelto claims that over seven million people worldwide have been prescribed Xarelto, and that six million prescriptions have been written in the U.S.

78. During the Defendants' 2012 fiscal year, Xarelto had approximately \$658 million in sales worldwide. Then, in 2013, sales for Xarelto increased even further to more than clear the \$1 billion threshold commonly referred to as "blockbuster" status in the pharmaceutical industry,

ultimately reaching approximately \$2 billion for the fiscal year. Thus, Xarelto is now considered the leading anticoagulant on a global scale in terms of sales.

79. As part of their marketing of Xarelto, Defendants widely disseminated direct-to-consumer advertising campaign that were designed to influence patients, including Decedent, to make inquiries to their prescribing physician about Xarelto and request prescriptions for Xarelto.

80. In the course of these direct to consumer advertisements, Defendants overstated the efficacy of Xarelto with respect to preventing stroke and systemic embolism, failed to adequately disclose to patients that there is no drug, agent, or means to reverse the anticoagulation effects of Xarelto, and that such irreversibility would have life-threatening and fatal consequences.

81. On June 6, 2013, Defendants received a letter from the FDA's Office of Prescription Drug Promotion (hereinafter referred to as the "OPDP") criticizing its promotional material for the atrial fibrillation indication, stating that, "the print ad is false or misleading because it minimizes the risks associated with Xarelto and makes a misleading claim" regarding dose adjustments, which was in violation of FDA regulations. The OPDP thus requested that Defendants immediately cease distribution of such promotional material.

82. Prior to Decedent's use of Xarelto, Decedent became aware of the promotional materials described herein.

83. Prior to Decedent's use of Xarelto, Decedent's prescribing physician received promotional materials and information from sales representatives of Defendants that Xarelto was just as effective as warfarin in reducing strokes in patients with non-valvular atrial fibrillation, as well as preventing DVT/PE in patients with prior history of DVT/PE or undergoing hip or knee replacement surgery, and was more convenient, without also adequately informing prescribing physicians that there was no reversal agent that could stop or control bleeding in patients taking Xarelto.

84. At all times relevant hereto, Defendants also failed to warn emergency room doctors, surgeons, and other critical care medical professionals that unlike generally-known measures taken to treat and stabilize bleeding in users of warfarin, there is no effective agent to reverse the anticoagulation effects of Xarelto, and therefore no effective means to treat and stabilize patients who experience uncontrolled bleeding while taking Xarelto.

85. At all times relevant to this action, The Xarelto Medication Guide, prepared and distributed by Defendants and intended for U.S. patients to whom Xarelto has been prescribed, failed to warn and disclose to patients that there is no agent to reverse the anticoagulation effects of Xarelto and that if serious bleeding occurs, it may be irreversible and life-threatening.

86. In the year leading up to June 30, 2012, there were 1,080 Xarelto-associated "Serious Adverse Event" ("SAE") MedWatch reports filed with the FDA, including at least 65 deaths. Of the reported hemorrhage events associated with Xarelto, 8% resulted in death, which was approximately twofold the risk of a hemorrhage-related death with warfarin.

87. At the close of the 2012 fiscal year, a total of 2,081 new Xarelto-associated SAE reports were filed with the FDA in its first full year on the market, ranking tenth among other pharmaceuticals in direct reports to the FDA. Of those reported events, 151 resulted in death, as compared to only 56 deaths associated with warfarin.

88. The ISMP referred to these SAE figures as constituting a "strong signal" regarding the safety of Xarelto, defined as "evidence of sufficient weight to justify an alert to the public and the scientific community, and to warrant further investigation."

89. Of particular note, in the first quarter of 2013, the number of reported serious adverse events associated with Xarelto (680) overtook that of Pradaxa (528), another new oral anticoagulant, which had previously ranked as the number one reported drug in terms of adverse events in 2012.

90. Moreover, on a global scale, in the first eight months of 2013, German regulators received 968 Xarelto-related adverse event reports, including 72 deaths, as compared to a total of 750 reports and 58 deaths in 2012.

91. Despite the clear signal generated by the SAE data, Defendants failed to either alert the public and the scientific community, or perform further investigation into the safety of Xarelto.

92. Defendants product labeling and prescribing information for Xarelto:

- (a) failed to investigate, research, study and define, fully and adequately, the safety profile of Xarelto;
- (b) failed to provide adequate warnings about the true safety risks associated with the use of Xarelto;

- (c) failed to provide adequate warning regarding the pharmacokinetic and pharmacodynamic variability of Xarelto and its effects on the degree of anticoagulation in a patient;
- (d) failed to provide adequate warning that it is difficult or impossible to assess the degree and extent of anticoagulation in patients taking Xarelto;
- (e) failed to disclose in the "Warnings" Section that there is no drug, agent or means to reverse the anticoagulation effects of Xarelto;
- (f) failed to advise prescribing physicians, such as the Decedent's physician, to instruct patients that there was no agent to reverse the anticoagulant effects of Xarelto;
- (g) failed to provide adequate instructions on how to intervene and stabilize a patient who suffers a bleed while taking Xarelto;
- (h) failed to provide adequate warnings and information related to the increased risks of bleeding events associated with aging patient populations of Xarelto users;
- (i) failed to provide adequate warnings regarding the increased risk of gastrointestinal bleeds in those taking Xarelto, especially, in those patients with a prior history of gastrointestinal issues and upset;
- (j) failed to provide adequate warnings regarding the increased risk of suffering a bleeding event, requiring blood transfusions in those taking Xarelto;
- (k) failed to provide adequate warnings regarding the need to assess renal functioning prior to starting a patient on Xarelto and to continue testing and monitoring of renal functioning periodically while the patient is on Xarelto;
- (l) failed to provide adequate warnings regarding the need to assess hepatic functioning prior to starting a patient on Xarelto and to continue testing and monitoring of hepatic functioning periodically while the patient is on Xarelto;
- (m) failed to include a "BOXED WARNING" about serious bleeding events associated with Xarelto;
- (n) failed to include a "BOLDED WARNING" about serious bleeding events associated with Xarelto; and
- (o) in their "Medication Guide" intended for distribution to patients to whom Xarelto has been prescribed, Defendants failed to disclose to patients that there is no drug,

agent or means to reverse the anticoagulation effects of Xarelto and that if serious bleeding occurs, such irreversibility could have permanently disabling, life-threatening or fatal consequences.

93. During the years since first marketing Xarelto in the U.S., Defendants modified the U.S. labeling and prescribing information for Xarelto, which included additional information regarding the use of Xarelto in patients taking certain medications. Despite being aware of: (1) serious, and sometimes fatal, irreversible bleeding events associated with the use of Xarelto; and (2) 2,081 SAE MedWatch reports filed with the FDA in 2012 alone, including at least 151 deaths, Defendants nonetheless failed to provide adequate disclosures or warnings in their label as detailed in the preceding paragraph.

94. Prior to applying for and obtaining approval of Xarelto, Defendants knew or should have known that consumption of Xarelto was associated with and would cause the induction of life-threatening bleeding, and Defendants possessed at least one clinical scientific study, which evidence Defendants knew or should have known was a signal that life-threatening bleeding risk needed further testing and studies prior to its introduction to the market.

95. Despite life-threatening bleeding findings in a clinical trial and other clinical evidence, Defendants failed to adequately conduct complete and proper testing of Xarelto prior to filing their New Drug Application for Xarelto.

96. From the date Defendants received FDA approval to market Xarelto, Defendants made, distributed, marketed, and sold Xarelto without adequate warning to Decedent's prescribing physicians or Decedent that Xarelto was associated with and could cause life-threatening bleeding, presented a risk of life-threatening bleeding in patients who used it, and that Defendants had not adequately conducted complete and proper testing and studies of Xarelto with regard to severe side effects, specifically life-threatening bleeding.

97. Upon information and belief, Defendants concealed and failed to completely disclose its knowledge that Xarelto was associated with or could cause life-threatening bleeding as well as its knowledge that they had failed to fully test or study said risk.

98. Defendants ignored the association between the use of Xarelto and the risk of developing life-threatening bleeding.

99. Defendants' failure to disclose information that they possessed regarding the failure to adequately test and study Xarelto for life-threatening bleeding risk further rendered warnings for this medication inadequate.

100. By reason of the foregoing acts and omissions, Plaintiff has endured and continues to suffer emotional and mental anguish, loss of support, loss of services, loss of accumulations, medical and funeral expenses, and other economic and non-economic damages stemming from the death of the Decedent, as a result of the actions and inactions of the Defendants.

FIRST CAUSE OF ACTION
AS AGAINST THE DEFENDANTS (NEGLIGENCE)

101. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

102. Defendants had a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale and distribution of Xarelto into the stream of commerce, including a duty to assure that the product would not cause users to suffer unreasonable, dangerous side effects.

103. Defendants failed to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and distribution of Xarelto into interstate commerce in that Defendants knew or should have known that using Xarelto created a high risk of unreasonable, dangerous side effects, including, life-threatening bleeding, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and ultimately death.

104. The negligence of the Defendants, their agents, servants, and employees, included but was not limited to the following acts and omissions:

- (a) Manufacturing, producing, promoting, formulating, creating, and designing Xarelto without thoroughly testing it;
- (b) Manufacturing, producing, promoting, formulating, creating, and designing Xarelto without adequately testing it;

- (c) Not conducting sufficient testing programs to determine whether or not Xarelto was safe for use; in that Defendants herein knew or should have known that Xarelto was unsafe and unfit for use by reason of the dangers to its users;
- (d) Selling Xarelto without making proper and sufficient tests to determine the dangers to its users;
- (e) Negligently failing to adequately and correctly warn the Decedent, the public, the medical and healthcare profession, and the FDA of the dangers of Xarelto;
- (f) Failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use, Xarelto;
- (g) Failing to test Xarelto and failing to adequately, sufficiently and properly test Xarelto.
- (h) Negligently advertising and recommending the use of Xarelto without sufficient knowledge as to its dangerous propensities;
- (i) Negligently representing that Xarelto was safe for use for its intended purpose, when, in fact, it was unsafe;
- (j) Negligently representing that Xarelto had equivalent safety and efficacy as other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;
- (k) Negligently designing Xarelto in a manner which was dangerous to its users;
- (l) Negligently manufacturing Xarelto in a manner which was dangerous to its users;
- (m) Negligently producing Xarelto in a manner which was dangerous to its users;
- (n) Negligently assembling Xarelto in a manner which was dangerous to its users;
- (o) Concealing information from the Decedent in knowing that Xarelto was unsafe, dangerous, and non-conforming with FDA regulations;
- (p) Improperly concealing and misrepresenting information from the Decedent, healthcare professionals, and the FDA, concerning the severity of risks and dangers of Xarelto compared to other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non - valvular atrial fibrillation, reducing the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;

- (q) Negligently represented that one dose size fit all patients, whereas they knew or should have known that proper dosage depending on individualizing factors in users.

105. Defendants under-reported, underestimated and downplayed the serious dangers of Xarelto.

106. Defendants negligently compared the safety risk and dangers of Xarelto with other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

107. Defendants were negligent in the designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing and sale of Xarelto in that they:

- (a) Failed to use due care in designing and manufacturing Xarelto so as to avoid the aforementioned risks to individuals when Xarelto was used for treatment for reducing the risk of stroke and systemic embolism in patients with non - valvular atrial fibrillation, reducing the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;
- (b) Failed to accompany their product with proper and accurate warnings regarding all possible adverse side effects associated with the use of Xarelto;
- (c) Failed to accompany their product with proper warnings regarding all possible adverse side effects concerning the failure and malfunction of Xarelto;
- (d) Failed to accompany their product with accurate warnings regarding the risks of all possible adverse side effects concerning Xarelto;
- (e) Failed to warn Decedent of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity of the side effects;
- (f) Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Xarelto;
- (g) Failed to warn Decedent, prior to actively encouraging the sale of Xarelto, either directly or indirectly, orally or in writing, about the need for more comprehensive, more regular medical monitoring than usual to ensure early discovery of potentially serious side effects;

- (h) Failed to instruct how to adjust the dosage to the particular patient and instead stated misleadingly that one dosage fit all patients;
- (i) Were otherwise careless and negligent.

108. Despite the fact that Defendants knew or should have known that Xarelto caused unreasonably dangerous side effects, Defendants continued and continue to market, manufacture, distribute and sell Xarelto to consumers, including the Decedent.

109. Defendants knew or should have known that consumers such as the Decedent would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

110. Defendants' negligence was the proximate cause of Decedent's injuries, harm and economic loss, which Decedent suffered.

111. As a result of the foregoing acts and omissions, the Decedent was caused to sufferer serious and dangerous side effects including, life-threatening bleeding, as well as other severe and person injuries which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, shortened life expectancy, expenses for hospitalization, loss of earnings and ultimately death.

112. As a result of the foregoing acts and omissions, Decedent's estate has suffered and incurred damages, including medical expenses; the loss of accumulations; probate, attorney, accountant, and other fees and costs of an administration; and other economic and non-economic damages flowing from the death of the Decedent.

113. By reason of the foregoing, Decedent and Plaintiff have suffered injuries and damages as alleged herein.

SECOND CAUSE OF ACTION AS AGAINST THE DEFENDANTS
(STRICT PRODUCTS LIABILITY)

114. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

115. At all times herein mentioned, the Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed, and have recently

acquired the Defendants who have designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed Xarelto as hereinabove described that was used by the Decedent. That Xarelto was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendants.

116. At those times, Xarelto was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, and in particular, the Decedent herein.

117. The Xarelto designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective in design or formulation in that, when it left the hands of the manufacturer and suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of Xarelto.

118. The Xarelto designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective in design and formulation, in that, when it left the hands of the Defendants, manufacturers, and suppliers, it was unreasonably dangerous, and it was more dangerous than an ordinary consumer would expect.

119. At all times herein mentioned, Xarelto was in a defective condition and unsafe, and Defendants knew or had reason to know that said product was defective and unsafe, especially when used in the form and manner as provided by the Defendants.

120. Defendants knew, or should have known that at all times herein mentioned, that Xarelto was in a defective condition, and was and is inherently dangerous and unsafe.

121. At the time of the Decedent's use of Xarelto, Xarelto was being used for the purposes and in a manner normally intended, namely for his diagnosed atrial fibrillation.

122. Defendants with this knowledge voluntarily designed its Xarelto in a dangerous condition for use by the public, and in particular the Decedent.

123. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended use.

124. Defendants created a product unreasonably dangerous for its normal, intended use.

125. The Xarelto designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was manufactured defectively in that Xarelto left

the hands of Defendants in a defective condition and was unreasonably dangerous to its intended users.

126. Xarelto as designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants reached their intended users in the same defective and unreasonably dangerous condition in which the Defendants' Xarelto was manufactured.

127. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk to the health of consumers and to the Decedent in particular; and Defendants are therefore strictly liable for the injuries sustained by the Decedent.

128. The Decedent could not, by the exercise of reasonable care, have discovered Xarelto's defects herein mentioned and perceived its danger.

129. Xarelto as designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate warnings or instructions, as the Defendants knew or should have known that the product created a risk of serious and dangerous side effects including, life-threatening bleeding, as well as other severe and personal injuries which are permanent and lasting in nature and the Defendants failed to adequately warn of said risk.

130. Xarelto as designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate warnings and inadequate testing.

131. Xarelto as designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate post-marketing surveillance and warnings because, after Defendants knew or should have known of the risks of serious side effects including, life-threatening bleeding, as well as other severe and permanent health consequences from Xarelto, they failed to provide adequate warnings to users or consumers of the product, and continued to improperly advertise, market and promote their product, Xarelto.

132. By reason of the foregoing, the Defendants have become strictly liable in tort to the Decedent for the manufacturing, marketing, promoting, distribution, and selling of a defective product, Xarelto.

133. Defendants' defective design, manufacturing defect, and inadequate warnings of Xarelto were acts that amount to willful, wanton, and reckless conduct by Defendants.

134. That said defects in Defendants' drug Xarelto were a substantial factor in causing Decedent's injuries.

135. As a result of the foregoing acts and omissions, the Decedent was caused to sufferer serious and dangerous side effects including, life-threatening bleeding, as well as other severe and person injuries, physical pain and mental anguish, diminished enjoyment of life, shortened life expectancy, expenses for hospitalization, loss of earnings and ultimately death.

136. As a result of the foregoing acts and omissions, the Decedent was caused to sufferer serious and dangerous side effects including, life-threatening bleeding, as well as other severe and person injuries which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, shortened life expectancy, expenses for hospitalization, loss of earnings and ultimately death.

137. As a result of the foregoing acts and omissions, Decedent's estate has suffered and incurred damages, including medical expenses; the loss of accumulations; probate, attorney, accountant, and other fees and costs of an administration; and other economic and non-economic damages flowing from the death of the Decedent.

138. By reason of the foregoing, Decedent and Plaintiff have suffered injuries and damages as alleged herein.

THIRD CAUSE OF ACTION AS AGAINST THE DEFENDANTS
(BREACH OF EXPRESS WARRANTY)

139. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

140. Defendants expressly warranted that Xarelto was safe and well accepted by users.

141. Xarelto does not conform to these express representations because Xarelto is not safe and has numerous serious side effects, many of which were not accurately warned about by Defendants. As a direct and proximate result of the breach of said warranties, Decedent and

142. Plaintiff suffered and will continue to suffer severe and permanent personal injuries, harm and economic loss.

143. Decedent did rely on the express warranties of the Defendants herein.

144. Members of the medical community, including physicians and other healthcare professionals, relied upon the representations and warranties of the Defendants for use of Xarelto in recommending, prescribing, and dispensing Xarelto.

145. The Defendants herein breached the aforesaid express warranties, as their drug Xarelto was defective.

146. Defendants expressly represented to Decedent, Decedent's physicians, healthcare providers, and the FDA that Xarelto was safe and fit for use for the purposes intended, that it was of merchantable quality, that it did not produce any dangerous side effects in excess of those risks associated with other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery, that the side effects it did produce were accurately reflected in the warnings and that it was adequately tested and fit for its intended use.

147. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that Xarelto was not safe and fit for the use intended, and, in fact, produced serious injuries to the users that were not accurately identified and represented by Defendants.

148. As a result of the foregoing acts and omissions, the Decedent was caused to sufferer serious and dangerous side effects including, life-threatening bleeding, as well as other severe and person injuries which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, shortened life expectancy, expenses for hospitalization, loss of earnings and ultimately death.

149. As a result of the foregoing acts and omissions, Decedent's estate has suffered and incurred damages, including medical expenses; the loss of accumulations; probate, attorney, accountant, and other fees and costs of an administration; and other economic and non-economic damages flowing from the death of the Decedent.

150. By reason of the foregoing, Decedent and Plaintiff have suffered injuries and damages as alleged herein.

FOURTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS
(BREACH OF IMPLIED WARRANTIES)

151. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

152. At all times herein mentioned, the Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Xarelto and have recently acquired the Defendants who have manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Xarelto, to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation.

153. At the time Defendants marketed, sold, and distributed Xarelto for use by Decedent, Defendants knew of the use for which Xarelto was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

154. The Defendants impliedly represented and warranted to the users of Xarelto and their physicians, healthcare providers, and the FDA that Xarelto was safe and of merchantable quality and fit for the ordinary purpose for which said product was to be used.

155. That said representations and warranties aforementioned were false, misleading, and inaccurate in that Xarelto was unsafe, unreasonably dangerous, improper, not of merchantable quality, and defective.

156. Decedent, and members of the medical community and healthcare professionals did rely on said implied warranty of merchantability of fitness for a particular use and purpose.

157. Decedent and Decedent's physicians and healthcare professionals reasonably relied upon the skill and judgment of Defendants as to whether Xarelto was of merchantable quality and safe and fit for its intended use.

158. Xarelto was injected into the stream of commerce by the Defendants in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

159. The Defendants herein breached the aforesaid implied warranties, as their drug Xarelto was not fit for its intended purposes and uses.

160. As a result of the foregoing acts and omissions, the Decedent was caused to sufferer serious and dangerous side effects including, life-threatening bleeding, as well as other severe and person injuries which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, shortened life expectancy, expenses for hospitalization, loss of earnings and ultimately death.

161. As a result of the foregoing acts and omissions, Decedent's estate has suffered and incurred damages, including medical expenses; the loss of accumulations; probate, attorney, accountant, and other fees and costs of an administration; and other economic and non-economic damages flowing from the death of the Decedent

162. By reason of the foregoing, Decedent and Plaintiff have suffered injuries and damages as alleged herein.

FIFTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS
(FRAUDULENT MISREPRESENTATION)

163. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

164. The Defendants falsely and fraudulently represented to the medical and healthcare community, Decedent's prescribing physician, and to the Decedent, and the FDA, and the public in general, that said product, Xarelto, had been tested and was found to be safe and effective to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat DVT and PE, to reduce the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

165. That representations made by Defendants were, in fact, false.

166. When said representations were made by Defendants, they knew those representations to be false and it willfully, wantonly and recklessly disregarded whether the representations were true.

167. These representations were made by said Defendants with the intent of defrauding and deceiving the Decedent, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, prescribe, dispense and purchase said

product, Xarelto, for use to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to reduce the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Decedent herein.

168. At the time the aforesaid representations were made by the Defendants and, at the time the Decedent used Xarelto, the Decedent was unaware of the falsity of said representations and reasonably believed them to be true.

169. In reliance upon said representations, the Decedent was induced to and did use Xarelto, thereby sustaining severe and permanent personal injuries.

170. Said Defendants knew and were aware or should have been aware that Xarelto had not been sufficiently tested, was defective in nature, and that it lacked adequate and sufficient warnings.

171. Defendants knew or should have known that Xarelto had a potential to, could, and would cause severe and grievous injury to the users of said product, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate, and down-played warnings.

172. Defendants brought Xarelto to the market, and acted fraudulently, wantonly and maliciously to the detriment of the Decedent.

173. As a result of the foregoing acts and omissions, the Decedent was caused to sufferer serious and dangerous side effects including, life-threatening bleeding, as well as other severe and person injuries which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, shortened life expectancy, expenses for hospitalization, loss of earnings and ultimately death.

174. As a result of the foregoing acts and omissions, Decedent's estate has suffered and incurred damages, including medical expenses; the loss of accumulations; probate, attorney, accountant, and other fees and costs of an administration; and other economic and non-economic damages flowing from the death of the Decedent.

175. By reason of the foregoing, Decedent and Plaintiff have suffered injuries and damages as alleged herein.

SIXTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS
(FRAUDULENT CONCEALMENT)

176. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

177. At all times during the course of dealing between Defendants and Decedent, and Decedent's healthcare providers, and the FDA, Defendants misrepresented the safety of Xarelto for its intended use.

178. Defendants knew or were reckless in not knowing that its representations were false.

179. In representations to Decedent, and Decedent's healthcare providers, and the FDA, Defendants fraudulently concealed and intentionally omitted the following material information:

- (a) that Xarelto was not as safe as other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;
- (b) that the risks of adverse events with Xarelto were higher than those with other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients • undergoing hip and knee replacement surgery;
- (c) that the risks of adverse events with Xarelto were not adequately tested and known by Defendants;
- (d) that Defendants were aware of dangers in Xarelto, in addition to and above and beyond those associated with other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;
- (e) that Xarelto was defective, and that it caused dangerous side effects, including but not limited to life-threatening bleeding, as well as other severe and permanent health consequences, in a much more and significant rate than other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial

fibrillation, reducing the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;

- (f) that patients needed to be monitored more regularly than normal while using Xarelto;
- (g) that Xarelto was manufactured negligently;
- (h) that Xarelto was manufactured defectively;
- (i) that Xarelto was manufactured improperly;
- (j) that Xarelto was designed negligently;
- (k) that Xarelto was designed defectively; and
- (l) that Xarelto was designed improperly.

180. Defendants were under a duty to disclose to Decedent, and Decedent's physicians, hospitals, healthcare providers, and the FDA the defective nature of Xarelto, including but not limited to the heightened risks of life-threatening bleeding.

181. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects, and hence, cause damage to persons who used Xarelto, including the Decedent, in particular.

182. Defendants' concealment and omissions of material facts concerning the safety of Xarelto was made purposefully, willfully, wantonly, and recklessly, to mislead Decedent, and Decedent's physicians, hospitals and healthcare providers into reliance, continued use of Xarelto, and actions thereon, and to cause them to purchase, prescribe, and dispense Xarelto and use the product.

183. Defendants knew that Decedent, and Decedent's physicians, hospitals, healthcare providers, and the FDA had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding Xarelto, as set forth herein.

184. Decedent, as well as Decedent's doctors, healthcare providers, and hospitals reasonably relied on facts revealed which negligently, fraudulently and purposefully did not include facts that were concealed and omitted by Defendants.

185. As a result of the foregoing acts and omissions, the Decedent was caused to sufferer serious and dangerous side effects including, life-threatening bleeding, as well as other severe and person injuries which are permanent and lasting in nature, physical pain and mental

anguish, diminished enjoyment of life, shortened life expectancy, expenses for hospitalization, loss of earnings and ultimately death.

186. As a result of the foregoing acts and omissions, Decedent's estate has suffered and incurred damages, including medical expenses; the loss of accumulations; probate, attorney, accountant, and other fees and costs of an administration; and other economic and non-economic damages flowing from the death of the Decedent.

187. By reason of the foregoing, Decedent and Plaintiff have suffered injuries and damages as alleged herein.

SEVENTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS
(NEGLIGENT MISREPRESENTATION)

188. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

189. Defendants had a duty to represent to the medical and healthcare community, and to the Decedent, the FDA, and the public in general that said product, Xarelto, had been tested and found to be safe and effective to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to reduce the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

190. The representations made by Defendants were, in fact, false.

191. Defendants failed to exercise ordinary care in the representation of Xarelto, while involved in its manufacture, sale, testing, quality assurance, quality control, and distribution of said product into interstate commerce, in that Defendants negligently misrepresented Xarelto's high risk of unreasonable, dangerous side effects.

192. Defendants breached their duty in representing Xarelto's serious side effects to the medical and healthcare community, to the Decedent, the FDA and the public in general.

193. As a result of the foregoing acts and omissions, the Decedent was caused to sufferer serious and dangerous side effects including, life-threatening bleeding, as well as other severe and person injuries which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, shortened life expectancy, expenses for hospitalization, loss of earnings and ultimately death.

194. As a result of the foregoing acts and omissions, Decedent's estate has suffered and incurred damages, including medical expenses; the loss of accumulations; probate, attorney, accountant, and other fees and costs of an administration; and other economic and non-economic damages flowing from the death of the Decedent.

195. By reason of the foregoing, Decedent and Plaintiff have suffered injuries and damages as alleged herein.

EIGHTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS
(FRAUD AND DECEIT)

196. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

197. Defendants conducted research, or lack thereof, and used Xarelto as part of their research.

198. As a result of Defendants' research and testing, or lack thereof, Defendants blatantly and intentionally distributed false information, including but not limited to assuring the public, the Decedent, Decedent's doctors, hospitals, healthcare professionals, and the FDA that Xarelto was safe and effective for use as a means to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to reduce the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

199. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally omitted certain results of testing and research to the public healthcare professionals, and the FDA, including the Decedent.

200. Defendants had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and the Decedent, as well as Decedent's respective healthcare providers and the FDA.

201. The information distributed to the public, the FDA, and the Decedent, by Defendants, including but not limited to reports, press releases, advertising campaigns, television commercials, print ads, magazine ads, billboards, and all other commercial media contained material representations of fact and omissions.

202. The information distributed to the public, the FDA, and the Decedent, by Defendants intentionally included representations that Defendants' drug Xarelto was safe and effective for use to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to reduce the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

203. The information distributed to the public, the FDA, and the Decedent, by Defendants intentionally included representations that Defendants' drug Xarelto carried the same risks, hazards, and dangers as other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

204. The information distributed to the public, the FDA, and the Decedent, by Defendants intentionally included false representations that Xarelto was not injurious to the health and safety of its intended users.

205. The information distributed to the public, the FDA, and the Decedent, by Defendants intentionally included false representations that Xarelto was as potentially injurious to the health and safety of its intended users, as other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

206. These representations were all false and misleading.

207. Upon information and belief, Defendants intentionally suppressed, ignored and disregarded test results not favorable to the Defendants, and results that demonstrated that Xarelto was not safe as a means of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery, and was not as safe as other means of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

208. Defendants intentionally made material representations to the FDA and the public, including the medical profession, and the Decedent, regarding the safety of Xarelto,

specifically but not limited to Xarelto not having dangerous and serious health and safety concerns.

209. Defendants intentionally made material representations to the FDA and the public in general, including the medical profession, and the Decedents, regarding the safety of Xarelto, specifically but not limited to Xarelto being a safe means of reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

210. It was the purpose of Defendants in making these representations to deceive and defraud the public, the FDA, and the Decedent, to gain the confidence of the public, healthcare professionals, the FDA, and the Decedent, to falsely ensure the quality and fitness for use of Xarelto and induce the public, and the Decedent to purchase, request, dispense, prescribe, recommend, and continue to use Xarelto.

211. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and the Decedent that Xarelto was fit and safe for use as treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

212. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and the Decedent that Xarelto was fit and safe for use as treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery, and did not pose risks, dangers, or hazards above and beyond those identified and associated with other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

213. Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Decedent that Xarelto did not present serious health and safety risks.

214. Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Decedent that Xarelto did not present health and safety risks greater than other oral forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

215. These representations and others made by Defendants were false when made, and were made with a pretense of actual knowledge when knowledge did not actually exist, and were made recklessly and without regard to the actual facts.

216. These representations and others, made by Defendants, were made with the intention of deceiving and defrauding the Decedent, including Decedent's respective healthcare professionals and the FDA, and were made in order to induce the Decedent and Decedent's respective healthcare professionals to rely upon misrepresentations and caused the Decedent to purchase, use, rely on, request, dispense, recommend, and prescribe Xarelto

217. Defendants, recklessly and intentionally falsely represented the dangerous and serious health and safety concerns of Xarelto to the public at large, the Decedent in particular, for the purpose of influencing the marketing of a product known to be dangerous and defective and not as safe as other alternatives, including other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

218. Defendants willfully and intentionally failed to disclose the material facts regarding the dangerous and serious safety concerns of Xarelto by concealing and suppressing material facts regarding the dangerous and serious health and safety concerns of Xarelto.

219. Defendants willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations with the purpose and design of deceiving and lulling the Decedent, as well as his respective healthcare professionals into a sense of security so that Decedent would rely on the representations made by Defendants, and purchase, use and rely on Xarelto and that Decedent's respective healthcare providers would dispense, prescribe, and recommend the same.

220. Defendants, through their public relations efforts, which included but were not limited to the public statements and press releases, knew or should have known that the public, including the Decedent, as well as Decedent's respective healthcare professionals would rely upon the information being disseminated.

221. Defendants utilized direct to consumer advertising to market, promote, and advertise Xarelto.

222. The Decedent and Decedent's respective healthcare professionals did in fact rely on and believe the Defendants' representations to be true at the time they were made and relied upon the representations as well as the superior knowledge of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery, and were thereby induced to purchase, use and rely on Defendants' drug Xarelto.

223. The Decedent and Decedent's respective healthcare providers did not know the truth with regard to the dangerous and serious health and safety concerns of Xarelto.

224. That the Decedent did not discover the true facts with respect to the dangerous and serious health and safety concerns, and the false representations of Defendants, nor could the Decedent with reasonable diligence have discovered the true facts.

225. Had Decedent known the true facts with respect to the dangerous and serious health and safety concerns of Xarelto, Decedent would not have purchased, used and relied on Defendants' drug Xarelto.

226. The Defendants' aforementioned conduct constitutes fraud and deceit, and was committed and perpetrated willfully, wantonly and purposefully on the Decedent.

227. As a result of the foregoing acts and omissions, the Decedent was caused to sufferer serious and dangerous side effects including, life-threatening bleeding, as well as other severe and person injuries which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, shortened life expectancy, expenses for hospitalization, loss of earnings and ultimately death.

228. As a result of the foregoing acts and omissions, the Decedent was caused to sufferer serious and dangerous side effects including, life-threatening bleeding, as well as other severe and person injuries which are permanent and lasting in nature, physical pain and mental

anguish, diminished enjoyment of life, shortened life expectancy, expenses for hospitalization, loss of earnings and ultimately death.

229. As a result of the foregoing acts and omissions, Decedent's estate has suffered and incurred damages, including medical expenses; the loss of accumulations; probate, attorney; accountant, and other fees and costs of an administration; and other economic and non-economic damages flowing from the death of the Decedent.

230. By reason of the foregoing, Decedent and Plaintiff have suffered injuries and damages as alleged herein.

NINTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS
(VIOLATION OF CONSUMER PROTECTION LAWS)

231. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

232. Defendants have a statutory duty to refrain from making false or fraudulent representations and from engaging in deceptive acts or practices in the sale and promotion of Xarelto pursuant to Rhode Island consumer protection laws. .

233. Defendants engaged in unfair, deceptive, false and fraudulent acts and practices in violation of Rhode Island law through its false and misleading promotion of Xarelto designed to induce Decedent to purchase and use Xarelto.

234. Defendants' conduct as described herein constituted unfair and deceptive acts and practices, including, but not limited to:

- (a) Publishing instructions and product material containing inaccurate and incomplete factual information;
- (b) Misrepresenting the nature, quality, and characteristics about the product; and
- (c) Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

235. Defendants misrepresented the alleged benefits of Xarelto, failed to disclose material information concerning known side effects of Xarelto, misrepresented the quality of Xarelto, and otherwise engaged in fraudulent and deceptive conduct which induced Decedent to purchase and use Xarelto.

236. Defendants uniformly communicated the purported benefits of Xarelto while failing to disclose the serious and dangerous side-effects related to the use of Xarelto, its safety, its efficacy, and its usefulness. Defendants made these representations to physicians, the medical community at large, and to patients and consumers such as Decedent in the marketing and advertising campaign described herein.

237. Defendants' conduct in connection with Xarelto was impermissible and illegal in that it created a likelihood of confusion and misunderstanding, because Defendants misleadingly, falsely and or deceptively misrepresented and omitted numerous material facts regarding, among other things, the utility, benefits, costs, safety, efficacy and advantages of Xarelto.

238. Defendants' conduct as described above was a material cause of Decedent's decision to purchase Xarelto.

239. As a direct, foreseeable and proximate cause of Defendants' conduct in violation of Rhode Island law the Plaintiff and Decedent suffered damages, including personal injuries, economic damages, and non-economic damages. Defendants' conduct was further wanton, egregious, and reckless so as to warrant the award of punitive damages.

240. As a result of the foregoing acts and omissions, the Decedent was caused to sufferer serious and dangerous side effects including, life-threatening bleeding, as well as other severe and person injuries which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, shortened life expectancy, expenses for hospitalization, loss of earnings and ultimately death.

241. As a result of the foregoing acts and omissions, Decedent's estate has suffered and incurred damages, including medical expenses; the loss of accumulations; probate, attorney, accountant, and other fees and costs of an administration; and other economic and non-economic damages flowing from the death of the Decedent.

242. By reason of the foregoing, Decedent and Plaintiff have suffered injuries and damages as alleged herein.

TENTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS
(SURVIVAL ACTION)

243. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

244. Plaintiff has the right to bring the following survival action on behalf of Decedent pursuant to Rhode Island law.

245. All causes of action asserted in this Complaint survive the death of the Decedent.

246. As a result of the foregoing acts and omissions on the part of the Defendants, the Decedent died on February 14, 2013 and said death was proximately caused in whole or in part by the tortious conduct and negligence, recklessness and gross negligence of the Defendants herein.

247. Prior to Decedent's said death, Decedent was hospitalized for a subarachnoid hemorrhage and severe and irreversible bleeding that was caused by Defendants' Xarelto.

248. As a result of the foregoing acts and omissions, the Decedent was caused to suffer serious and dangerous side effects including, life-threatening bleeding, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including but not limited to, diminished enjoyment of life, shortened life, expectancy, expenses for hospitalization, loss of earnings and ultimately death.

249. Accordingly, the Plaintiff brings all such causes of action on behalf of the Decedent and in the name of the Decedent's Estate for these damages.

250. Plaintiff further pleads all survival damages allowed by the State of Rhode Island Survival Statute.

ELEVENTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS
(WRONGFUL DEATH ACTION)

251. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

252. All causes of actions asserted in this Complaint survive the death of the Decedent.

253. Plaintiff has the authority to bring the following Wrongful Death Action on behalf of the beneficiaries pursuant to the Rhode Island law.

254. As a result of the foregoing acts and omissions on the part of the Defendants, the Decedent died on Feb. 14, 1913 and said death was proximately caused in whole or in part by the tortious conduct and negligence, recklessness and gross negligence of the Defendants herein.

255. As a direct, foreseeable and proximate result of Defendants' aforementioned conduct, Decedent's estate has suffered and incurred damages, including medical expenses; the loss of accumulations; funeral expenses; probate, attorney, accountant, and other fees and costs of administration; and other economic and non-economic damages flowing from the death of the Decedent.

256. Plaintiff further pleads all wrongful death damages allowed by the State of Rhode Island.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against the Defendants on each of the above-referenced claims and Causes of Action and as follows:

257. Compensatory damages in excess of the jurisdictional amount, including, but not limited to pain, suffering, emotional distress, loss of enjoyment of life, and other non-economic damages in an amount to be determined at trial of this action;

258. Economic damages in the form of medical expenses, out of pocket expenses, lost earnings and other economic damages in an amount to be determine at trial of this action;

259. Punitive damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Decedent in an amount sufficient to punish Defendants and deter future similar conduct;

260. Prejudgment interest;

261. Postjudgment interest;

262. Awarding Plaintiff reasonable attorneys' fees;

263. Awarding Plaintiff the costs of these proceedings; and

264. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

265. Plaintiff hereby demands trial by jury as to all issues.

Dated: April 20, 2015

RHEINGOLD, VALET, RHEINGOLD
McCARTNEY & GIUFFRA LLP

By: /s/Thomas P. Giuffra

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